



UNITED STATES DEPARTMENT OF COMMERCE
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EXAMINER

KIM, J

ART UNIT

PAPER NUMBER

1614

8

DATE MAILED: 05/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/450,609

Applicant(s)

Helle Weibel et al.

Examiner

Jennifer Kim

Group Art Unit

1614



☒ Responsive to communication(s) filed on Mar 27, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) 3-5 and 17-19 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, and 6-16 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: Denmark PA 1998 01580

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Applicants' election without traverse of Group I, claims 1,2 and 6-16, drawn to pharmaceutical compositions in Paper No. 7 is acknowledged.

The claims have been examined only to the extent of applicants' election.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 9 are improper Markush group. They need to be rewritten by inserting "or" at the end of line 14 and line 30 respectively.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Lohray et al. (WO 9741097) disclosed by applicants and applicants' admission.

Applicants admit, at page 1, lines 7-11 of the specification, that applicants' active agent and pharmaceutically acceptable salts has been found useful in the treatment of type 2 diabetes acting as a insulin sensitizer as disclosed in WO9741097. Lohray et al. also teach at page 35, example, applicants' composition in a tablet form.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

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and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 6-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al.(WO 9741097) in view of Sohda et al.(U.S.Patent No.5972971).

Lohray et al. at page 34, lines 27-29, page 35, example, and page 7, lines 13-14, teach pharmaceutical composition containing applicants' active agent (see previous rejection) in tablet, capsule, or powder form, in combination with the pharmaceutically acceptable excipient set forth in claim 8-10, and flavourants, sweeteners set forth in claim 16, and other media normally employed in preparing such compositions.

Sohda et al. at abstract and column 10, lines 20-21, teach anti-diabetic agent containing anti-oxidants, preferably ascorbic acid. Sodha et al. also teach at column 9, lines 55-65, the anti-diabetic agent containing applicants' excipient such as lactose, mannitol, starch, crystalline cellulose, silicone dioxide, magnesium stearate, and hydroxy propyl methyl cellulose.

The difference between the primary reference and applicants' claimed invention is the presence of anti-oxidant set forth in claims 6,14, and 15, and the proportions set forth in claims 8 and 9.

However, to incorporate anti-oxidant to the primary reference would have been obvious to a person of ordinary skill in view of Sohda et al. who teach antidiabetic agent containing anti-oxidant and the other excipient. One in ordinary skill in the art would have been motivated to

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combine anti-oxidants to the above composition since Lohray et al. teach other media normally employed can be incorporated and anti-oxidant is normally incorporated by Sohda et al. in formulating anti-diabetic agent.

The proportions of active agents to be used, and adjusting water content of excipient are all deemed obvious since they are all within the knowledge of the skilled pharmacologist.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

It is suggested, to advance the prosecution of the subject application, that a side by side comparison of stability be performed and results submitted per Rule 1.132 for review by the Patent Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is (703) 308-2232. The examiner can normally be reached on Monday through Friday from 9 AM. to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-7924.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

jmk

April 14, 2000


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